



UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

HUMAN GENOME SCIENCES INC.
INTELLECTUAL PROPERTY DEPT.
14200 SHADY GROVE ROAD
ROCKVILLE MD 20850

COPY MAILED

SEP 14 2009

OFFICE OF PETITIONS

In re Application of :
Rosen et al. :
Application No. 10/602,727 : ON APPLICATION FOR
Filed: June 25, 2003 : PATENT TERM ADJUSTMENT
Attorney Docket No. PF596PIN :
:

This is in response to the "Application For Patent Term Adjustment Under 37 CFR §1.705(b)," filed March 6, 2009. Applicants request that the initial determination of patent term adjustment under 35 U.S.C. 154(b) be corrected from four hundred (400) days to five hundred ninety-four (594) days.

The application for patent term adjustment is DISMISSED.

On December 10, 2008, the Office mailed the Determination of Patent Term Adjustment under 35 U.S.C. 154(b) in the above-identified application. The Notice stated the patent term adjustment to date is 400 days. Applicants dispute the four-day reduction for the submission of an Information Disclosure Statement (IDS) on July 11, 2006. Applicants also contend that the Notice to Comply mailed on October 13, 2006 was not a proper response under 35 USC § 154(b)(1)(A)(ii) and 37 CFR §§1.702(a)(2) & 1.703(a)(2) to applicants July 7, 2006 reply.

Applicants contend that a 4-day reduction for the submission of the supplemental reply in the form of an Information Disclosure Statement (IDS) on July 11, 2006 is not warranted. Applicants argue that a complete reply to the March 7, 2006 restriction requirement was submitted on July 7, 2006, thus the submission

of the IDS was not a supplemental paper within the meaning of 37 CFR 1.704(c)(8). Further applicants contend that the submission of the IDS could not have delayed the examiners consideration because the reply was not forwarded to the examiner until July 11, 2006.

A period of reduction of 4 days was properly entered based on 37 CFR 1.704(c)(8). The reduction is not calculated based upon the date the reply is forwarded to the examiner. 37 CFR §1.704(c)(8) provides that a period of reduction is entered for:

Circumstances that constitute a failure of the applicant to engage in reasonable efforts to conclude processing or examination of an application also include the following circumstances, which will result in the following reduction of the period of adjustment set forth in § 1.703 to the extent that the periods are not overlapping:

- (8) Submission of a supplemental reply or other paper, other than a supplemental reply or other paper expressly requested by the examiner, after a reply has been filed, in which case the period of adjustment set forth in § 1.703 shall be reduced by the number of days, if any, beginning on the day after the date the initial reply was filed and ending on the date that the supplemental reply or other such paper was filed;

However, 37 CFR 1.704(d) provides that:

A paper containing only an information disclosure statement in compliance with §§ 1.97 and 1.98 will not be considered a failure to engage in reasonable efforts to conclude prosecution (processing or examination) of the application under paragraphs (c)(6), (c)(8), (c)(9), or (c)(10) of this section if it is accompanied by a statement that each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart application and that this communication was not received by any individual designated in § 1.56(c) more than thirty days prior to the filing of the information disclosure statement. This thirty-day period is not extendable.

In this instance, after the filing of a response on July 7, 2006, on July 11, 2006, applicants filed a supplemental paper in the form of an IDS. The record supports a conclusion that the IDS was not expressly requested by the examiner. Further, the IDS did not include the §1.704(d) statement. Accordingly, the PTA was properly reduced by 4 days, the number of days beginning on the day after the date the initial reply was filed, July 8, 2006, and ending on the date that the supplemental reply or other such paper was filed, July 11, 2006. As such the 4-day reduction was warranted and will not be removed.

Applicants also contend that instead of a 64-day adjustment a 254-day adjustment is required for the Office taking in excess of four months to reply to the response to the election requirement submitted on July 7, 2006. Applicants contend that the Notice to Comply to the Sequence Listing did not constitute a reply to the response to the restriction requirement. A period of adjustment of 254 days should have been entered based on 37 CFR 1.702(a)(2).

Applicants argument has been considered, but not found persuasive that entry of an additional period for Office delay is warranted.

37 CFR 1.704(c)(7) establishes submission of a reply having an omission (37 CFR 1.135(c)) as a circumstance that constitutes a failure of an applicant to engage in reasonable efforts to conclude processing or examination of an application. Submitting a reply having an omission requires the Office to issue an action under 37 CFR 1.135(c) and await and process the applicant's reply to the action under 37 CFR 1.135(c) before the initial reply (as corrected) can be treated on its merits. In addition, 37 CFR 1.704(c)(7) provides that in such a case the period of adjustment set forth in 37 CFR 1.703 shall be reduced by the number of days, if any, beginning on the day after the date the reply having an omission was filed and ending on the date that the reply or other paper correcting the omission was filed. The reference to 37 CFR 1.135(c) is parenthetical because 37 CFR 1.704(c)(7) is not limited to Office actions under 37 CFR 1.135(c) but applies when the Office issues any action or notice indicating that a reply has an omission which must be corrected: e.g., (1) a decision on a petition under 37 CFR 1.47 dismissing the petition as lacking an item necessary to grant the petition; or (2) a notice indicating that the computer readable format sequence listing filed in reply to a Notice to Comply with

Requirements for Patent Applications Containing Nucleotide Sequence and/or Amino Acid Sequence Disclosures (PTO-1661) does not comply with 37 CFR 1.821 et seq.

In this instance, the Office took action on October 13, 2006 in response to the response to the restriction requirement filed July 7, 2006 mailing an Office action that notified applicant that their response was considered *bonafide* but compliance with the sequence requirements was necessary. This Office communication was mailed within four months of the filing of the response, and thus, does not constitute Office delay. On January 16, 2007, applicants filed their response (which notably included an assertion that the new sequence listing is identical to the sequence listing currently on file, e.g. no omission), but also included an amendment.

It is concluded that the Office delay of 64 days was properly calculated based on the date of mailing of the Office action mailed July 19, 2007 in reply to the response to Notice to Comply filed January 16, 2007. A period of adjustment of 254 days will not be entered and the period of adjustment of 64 days will not be removed.

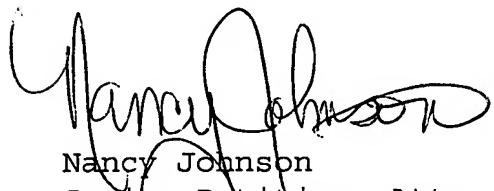
In view thereof, the determination of PTA at the time of the mailing of the notice of allowance remains FOUR HUNDRED (400) days.

The Office acknowledges submission of the \$200.00 fee set forth in 37 CFR 1.18(e). No additional fees are required.

Applicants are reminded that any delays by the Office pursuant to 37 CFR 1.702(a)(4) and 1.702(b) and any applicant delays under 37 CFR 1.704(c)(10) will be calculated at the time of the issuance of the patent and applicants will be notified of the revised patent term adjustment to be indicated on the patent in the Issue Notification letter that is mailed to applicants approximately three weeks prior to issuance.

The Office of Data Management has been advised of this decision. This matter is being referred to the Office of Data Management for issuance of the patent.

Telephone inquiries specific to this matter should be directed to the Petitions Attorney Charlema Grant at (571) 272-3215.



Nancy Johnson
Senior Petitions Attorney
Office of Petitions